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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

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EXAMINER
MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
1631	2

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/784,720	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner Channing S. Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-16.

Provisional Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q. 2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970);and, *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a no statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 1, 2, 5, and 9 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 09/784,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims define an invention which is a network and method for evaluating medical data with such similarity making the inventions to have overlapping embodiments. The aforementioned claims in the pending applications all maintain a network and method for evaluating medical data utilizing a biochip (containing biomolecular markers), a remote server (having a datalink and databank), and an expert system to evaluate test data.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Further, a notice of allowability for Application No. 09/784,571 has been sent, therefore should Application No. 09/784,571 become patented the above provisional obviousness-type double patenting rejection may required alteration.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986)

and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In order to create/utilize an "expert rule(s)/system" or "rules" one would require the disclosure of the steps/procedure to create/utilize said rules. It is acknowledged that expert rule(s)/system is indicated in the specification on page 1, line 26; page 2, line 15; page 4, lines 1 and 6; page 5, line 12; and page 9, lines 2, 3, 6, and 24, however, the specification fails to describe any steps/procedures of said expert rule(s)/system. Additionally, the specification fails to indicate any steps/procedures of the rule(s) as broadly claimed in instant claims 9-12. Said missing steps/procedures are essential to the use of the invention as claimed and therefore one of skill in the art cannot use the invention with the amount and direction presented, is therefore unpredictable, and would require undue experimentation.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims1 (line 26), 2 (line 2), 3 (line 1), 4(line 1), and all claims dependent therefrom recites the phrases "expert rule(s)", "expert evaluation system", and "expert system" which are vague and indefinite. It is unclear what applicants regard as "expert"; "expert implies a criteria which is considered "expert". Applicants can resolve this issue by particularly pointing out the criteria of "expert", via clearer claim wording.

Claims 1 (lines 26-27), 9 (line 25), and all claims dependent therefrom recites the phrase "improved diagnostic value" which is vague and indefinite. It is unclear as to the metes and bounds "improved" is to encompass, however, applicants can resolve this issue by particularly pointing out the criteria/range which encompasses "improved" (via clearer claim wording). Clarification is required.

Claims 1(lines 26-27), 9 (line 25), and all claims dependent therefrom recites the phrase "diagnostic value" implying a criteria to be applied to a value, thus making it diagnostic. It is unclear what criteria is applied/regarded as a "diagnostic value". Applicants can resolve this issue by particularly pointing out the applied/regard criteria for the diagnostic value of the metes and bounds of the claim, via clearer claim wording.

Claims 1 (line 27) and all claims dependent therefrom recites the term "using" which fails to indicate the metes and bounds of what is "using", thus the term is considered vague and indefinite. It is acknowledged that claim 1 (line 27) states "using all of said point of care raw data and all of said clinical data", however, applicants have failed to indicate steps for the evaluation system to create a new expert rule using all of said point of care raw data and all of said clinical data. Clarification of the metes and bounds of the claim, via clearer claim wording, is required.

Claims 2 (line 3) and all claims dependent therefrom recites the term "using" which fails to indicate the metes and bounds of what is "using", thus the term is considered vague and indefinite. It is acknowledged that claim 2 (lines 2-3) states "using said new expert rule to devise a measurement protocol", however, applicants have failed to indicate steps for the expert evaluation system to use said new expert rule to devise a measurement protocol. Clarification of the metes and bounds of the claim, via clearer claim wording, is required.

Claims 7 (line 5) and 15 (line 5) recite the phrase "augmented testing data" which is vague and indefinite. It is unclear as to the metes and bounds "augmented" is to encompass, however, applicants can resolve this issue by particularly pointing out the criteria/range which encompasses "augmented" (via clearer claim wording). Clarification is required.

Claims 9 (line 1) and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "a method for evaluating medical data in a clinical study", however the claim recites a final step of "creating a new rule". There is no indication that medical data is intended to be evaluated as resuscitated in the preamble. While minor details

are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the medical data is evaluated. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 13 (lines 5-6) and all claims dependent therefrom recites the phrase "use in said point of care test device for performing said diagnostic testing" which fails to indicate the metes and bounds of what is "use", thus the term is considered vague and indefinite. It is acknowledged that claim 13 (lines 5-6) states "use in said point of care test device for performing said diagnostic testing", however, applicants have failed to indicate steps for the utilization of the selected measurement protocol from said memory in said point of care test device for performing said diagnostic testing. Clarification of the metes and bounds of the claim, via clearer claim wording, is required.

LACK OF ANTECEDENT BASIS

Claims 1 (line 26), 2 (line 3), and all claims dependent therefrom recites the phrase "new expert rule" which lacks antecedent basis. The phrase "new expert rule" implies the existence of an "old" expert rule, there is no indication of an "old" expert rule nor the creation of an "old" expert rule in any of the preceding steps to the creation of a "new expert rule". Thus, a "new expert rule" fails to lack antecedent basis.

Claim 9 (line 25), 10 (lines 1-2), 11 (lines 1-2), 12 (lines 1-2), and all claims dependent therefrom recites the phrase "a new rule" which lacks antecedent basis. The phrase "new rule" implies the existence of an "old" rule, there is no indication of an "old" rule nor the creation of

an "old" rule in any of the preceding steps to the creation of "a new rule". Thus, "a new rule" fails to lack antecedent basis.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 9, 14, and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rindfleisch et al.

Rindfleisch et al. discusses the changes in the U.S. health care system, the need objective information to base health care decisions, and the clinical impact of genomic research (Abstract). The authors illustrate the flow of information from structured electronic medical records to research and clinical-trial data banks (Figure 1; i.e. network). Rindfleisch et al. states the need for ubiquitous and interoperating electronic medical record (EMR) systems to facilitate automatice interpretation of relations among data collected at multiple places for studying issues over broad populations (page 406, Column 1, lines 12-13). The development of microarrays (DNA sequences on silicon chips, glass slides, etc.) allows for the simultaneous screening of thousands of diseases; i.e. Affymetrix microarray for cystic fibrosis (CF). The DNA from a patient is broken down into short pieces and combined with a fluorescent compound, followed by binding/hybridization to a spot specific for a short sequence of DNA (biomarker encoding the normal or mutant form of a gene, i.e. CF) on the microarray, wherein results yield a fluorescent characteristic pattern (page 409, Column 2, lines 13-32; Intersection of Genomics Research and

Clinical Research section). Further, Affymetrix routinely makes diagnostic chips, which can test for 64,000 inherited sequences simultaneously (pages 409-410, Column 2-1, lines 34-35 and 1, respectively). Technology (i.e. microarray) is forging stronger ties between basic and clinical scientists to provide populations (patients via EMR) for studies of genomic function and to evaluate diagnostic and therapeutic interventions (page 410, Column 1, lines 28-31). The computer-based collection, management, and analysis of information will increase in importance (page 410, Column 1, lines 53-55). Thus, Rindfleisch et al. clearly anticipates the instantly claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rindfleisch et al. taken in view of Evans (U.S. Patent No. 5,924,174).

Rindfleisch et al. describes the implications of informatics in clinical and genomic research and discusses the development of a network system comprising microarrays and electronic medical records to aid in the collection, management, and analysis of patient information for the evaluation of diagnostic and therapeutic interventions, however, Rindfleisch et al. fails to describe an devised measurement protocol stored on a remote server for a selected pathology, characterization of a test result as a false positive, a false negative, or correct, and follow-up examination of the tested patient.

Evans describes an electronic medical records system (EMR) that creates and maintains all patient data electronically; wherein the system captures patient data (complaints, lab orders, medications, diagnoses, and procedures) at its source at the time of entry using a graphical user interface (Abstract). The system allows healthcare providers access, analysis, update, and annotation of patient data electronically through a computer network (Abstract). A large volume of patient information is created during the course of a patient's visit (including follow-up) to healthcare facilities, where a patient file comprises medical history, current treatments, medications prescribed, insurance, and other information (laboratory test results, physician's diagnosis, and treatments administered) (Column 1, lines 12-30). The EMR system includes the capability to manage a wide variety of patient data formats, including patient data from external sources, such as laboratories and pharmacies (Column 2, lines 39-42). The inventor illustrates structures of optional reference databases (diagnosis module, medication manager, and procedure module), which assists in diagnosing a patient's disease, prescribing medications, and ordering supplemental procedures to treat the disease (Figure 18 and Column 11, lines 10-30). Finally, Evans depicts one possible configuration of the EMR system (Figure 24).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Rindfleisch et al., network system comprising microarrays and EMR with Evans electronic medical record system with measurement protocols since Rindfleisch et al. states the need for integration of genomics and biomedical informatics for clinical researchers and providers (page 410, Column 2, lines 18-20). Further, Evans states that the described system is efficient, cost effective, eliminates the mishandling, loss and destruction of patient data (Column 14, lines 31-34 and 39-41).

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: September 6, 2002

Examiner Initials: CSM

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